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By Lynn Anderson

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Morris, *et al.*

SERIAL NO.: 09/938,276

FILED: August 22, 2001

FOR: TISSUE SURFACE TREATMENT  
APPARATUS AND METHOD

EXAMINER: Unknown

ART UNIT: 3731

Preliminary Amendment

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination, applicants respectfully request entry of the following amendments.

In the specification:

On page 6, please replace the paragraph starting on line 20 with the following:

Figures 9a-9b are bottom surface views illustrating an embodiment of a bendable tissue contacting surface with articulated sections.

On page 7, please replace the paragraph starting on line 8 with the following:

Figures 15a-15d are lateral views illustrating various alignments for the aperture and electrodes of the embodiment in Figure 7.

On page 7, please replace the paragraph starting on line 18 with the following:

Figure 21 is a lateral view illustrating an embodiment of an advancement member comprising one or more pushable advancement members with coupled electrodes.

On page 7, please replace the paragraph starting on line 21 with the following:

Figures 22a-22e are perspective views illustrating the use of the embodiment of the apparatus of Figure 13.

On page 7, please replace the paragraph starting on line 23 with the following:

Figure 20a is a lateral view illustrating an embodiment utilizing a push rod to advance the advancement member as well as the use of springs for retracting the advancement member.

On page 8, please replace the paragraph starting on line 1 with the following:

Figure 20b is a lateral view illustrating an embodiment utilizing a servomotor or solenoid to advance the advancing the advancement member.

On page 8, please replace the paragraph starting on line 4 with the following:

Figure 20c is a lateral view illustrating an embodiment utilizing pneumatic means to advance the advancing the advancement member as well as the use of vacuum source.

On page 8, please replace the paragraph starting on line 7 with the following:

Figure 20d is a lateral view illustrating an embodiment utilizing an inflatable balloon to advance the advancing the advancement member.

On page 8, please replace the paragraph starting on line 9 with the following:

Figure 22e is a lateral view illustrating an embodiment wherein the advancement member includes a cam to advance the advancement member.

On page 8, please replace the paragraph starting on line 12 with the following:

Figures 23a-23h are lateral views illustrating various configurations of the electrode including ring-like, ball, hemispherical, cylindrical, conical and needle-like.

On page 11, please delete the paragraph starting on line 4.

On page 11, please replace the paragraph starting on line 7 with the following:

Figure 46 is a schematic view illustrating an embodiment of the tissue contact surface having multiple conductive portions.

On page 11, please replace the paragraph starting on line 9 with the following:

Figure 47 is a schematic view illustrating an embodiment of a conductive tissue contact surface used to generate and control a current/energy vector within the target tissue volume.

On page 11, please replace the paragraph starting on line 12 with the following:

Figure 48 is a schematic view illustrating an embodiment of the surface treatment apparatus having a phased array of electrodes.

On page 11, please replace the paragraph starting on line 14 with the following:

Figure 49a is a flow chart illustrating an embodiment of a method of the invention utilizing an algorithm to switch between monopolar and bipolar modes based on measurement of tissue impedance.

On page 11, please replace the paragraph starting on line 17 with the following:

Figure 49b is schematic view of an embodiment of an apparatus for performing the method of Figure 49a.

On page 11, please replace the paragraph starting on line 19 with the following:

Figures 50a and 50b are lateral views illustrating embodiments of a collapsible strut surface treatment apparatus in a non-deployed and deployed state having a fixed distal hub.

On page 11, please replace the paragraph starting on line 22 with the following:

Figure 51 is a lateral view illustrating an alternative embodiment of the collapsible strut surface treatment apparatus having a movable distal hub.

On page 11, please replace the paragraph starting on line 25 with the following:

Figure 52 is a lateral view illustrating the use of the embodiment of Figure 50b or Figure 51 to produce multiple ablation volumes.

On page 12, please replace the paragraph starting on line 1 with the following:

Figure 53a is a lateral view illustrating an embodiment of a collapsible surface treatment apparatus utilizing an expandable balloon device.

On page 12, please replace the paragraph starting on line 4 with the following:

Figure 53b is a lateral view illustrating an embodiment of a collapsible surface treatment apparatus utilizing an expandable balloon device with a restraining member.

On page 12, please replace the paragraph starting on line 7 with the following:

Figure 54 is a block diagram illustrating a controller, power source, power circuits and other electronic components used with an embodiment of a control system other embodiments of the invention.

On page 12, please replace the paragraph starting on line 10 with the following:

Figure 55 is a block diagram illustrating an analog amplifier, analog multiplexer and microprocessor used with an embodiment of a control system other embodiments of the invention.

On page 13, please replace the paragraph starting on line 6 with the following:

Also, various embodiments are configured to treat not only accessible anterior portions of the liver but also posterior portions and/or portions obstructed by overlying or adjacent tissue and other organs and tissue. This capability is achieved through the use of components with sufficient flexibility and resiliency to bend, curve around or conform to tissue and anatomical structures including organs, bone and vasculature. Components of the apparatus of the invention having this flexibility can include the handpiece, housing and tissue contact surface described in detail herein. This flexibility enables the apparatus to not only be readily manipulated and positioned in at least partially obstructed tissue but also to deliver energy, fluids and apply pressure to and on obstructed or otherwise difficult to reach target tissue sites.

On page 17, please replace the paragraph starting on line 23 with the following:

Turning now to a discussion of the tissue contacting surface 14 (also called tissue contact surface 14), this component can have a variety of shapes including but not limited to circular, oval, rectangular, square and combinations thereof. Referring now to Figures 5a to 5e, contact surface 14 can have a variety of contours 14ctr including curved contours including convex or concave curved contours and combinations thereof. Additionally, the edges 14e of contacting portion 14 can be tapered 14t or radiused 14r.

On page 17, please replace the paragraph starting on line 1 with the following:

In a related embodiment, coating 12c can be a non-stick or lubricous coating 12lc configured to keep surface 14 or other portion of housing 12 or energy delivery 18 from sticking to tissue surface 5s before during or after ablation. This solves the problem of coagulated or burnt tissue undesirably sticking to surface 14 preventing its removal and/or causing unwanted tearing and other trauma to tissue surface 5s or tissue 5. Such coatings can include PTFE, TEFLON and other fluoro-carbon polymers, silicones, paralene and other low surface tension non-stick coatings known in the art.

On page 19, please replace the paragraph starting on line 8 with the following:

Referring to Figures 8 and 9a-9b, in other embodiments surface 14 can comprise one or more bendable sections 14b. In an embodiment shown in Figure 8, bendable sections 14b can include hinges 14h' to allow surface 14 to be moved and shaped by the physician prior to or during application of surface 14 to the target tissue surface. The hinges 14h' used can include those known in the art including spring loaded hinges giving the bendable sections 14b shape resilience. Hinges 14' can also include bearings, roller bearings, and miniature bearings such as those manufactured by RMB Miniature Bearings (Biel-Bienne, Switzerland). In a related embodiment shown in Figures 9a-9b, all or portion of surface 14 can include articulated sections 14as fabricated using known methods of articulated construction such as use of corrugated sections made using molding methods known in the art. Articulated sections 14as have a sufficient number of articulations 14as' to allow robust movement of surface 14 in one or more directions. Articulated sections 14as can be configured to bend or deflect with a selectable amount of applied force which can be in the range of 0.01 to 2 lbs with specific embodiment of 0.05, 0.1, 0.25, 0.5 and 1[bl]lb of force.

On page 19, please replace the paragraph starting on line 25 with the following:

Referring to Figures 10-14, in various embodiments, all or a portion of conformable surface 14 can be constructed from a porous material fluidly coupled to a fluid source and/or fluid delivery device described herein. In an embodiment shown in Figure 10, a porous portion or section 14p of surface 14 is configured to deliver a fluid film 14ff to target tissue surface 5s. Porous portion 14p can be made from a porous membrane or other porous material. Suitable porous materials can include but are not limited to foam, foam rubber, polyurethane foam, cellulose and woven or knitted DACRON, knitted polyester, continuous filament polyester, polyester-cellulose, rayon, polyamide, polyurethane, polyethylene and the like. The delivery of a fluid film in this manner can be configured to perform one or

more of the following functions: (i) produce a virtual fluid electrode adjacent or in the tissue surface to uniformly deliver RF energy to the selected tissue surface and underlying tissue when using a conductive solution; (ii) produce a virtual and electrically uniform ground pad electrode on the selected tissue surface to act as a return path for RF energy when using a conductive solution; and (iii) provide cooling over the selected tissue surface when a cooling solution is used which can also be a conductive solution. Porous surface 14p can have selectable and/or variable amounts of porosity. In one embodiment, porous portion 14p has uniform porosity and thickness so as to be able to achieve a substantially uniform delivery of fluid over porous portion surface 14ps. In another embodiment the porosity is varied over portion 14p including surface 14ps to produce varying amounts of fluid flow. For example, higher porosity on the perimeter to produce greater flows on the perimeter or edges of section 14p or alternatively greater porosities in the center portion. Also the porosity of section 14p can be controlled to retain fluid within the interior of section 14p in order to have section 14p act as a virtual or enhanced electrode 40 (described here in) including a virtual flexible electrode. Alternatively, one or more RF electrodes, such as plate or ring shaped RF electrodes 18, may be positioned within section 14p to both cool the electrode and conduct RF energy to section 14p to allow section 14p to act as an RF electrode to deliver RF energy to tissue surface 5s and underlying tissue.

On page 22, please replace the paragraph starting on line 15 with the following:

Referring to Figures 15a-15d, in various embodiments aperture 14a and electrode 18 can have different alignments including but not limited to the following: (i) aperture locus 14ac aligned with the centerline axis 18acl of electrode 18; (ii) aperture longitudinal axis 14aal substantially aligned with the electrode longitudinal axis 18al; and (iii) electrode longitudinal axis 18al substantially perpendicular to aperture plane 14ap.

On page 25, please replace the paragraph starting on line 14 with the following:

In an embodiment shown in Figure 21, advancement member 16 comprises one or more individual pushable advancement members 19 each coupled to or including an individual electrode 18 that is aligned with a corresponding apertures 14a so as to exit from aperture 14a. Pushable advancement members 19 can in turn be configured to be mechanically advanced by means of an advancement tool 21 that is configured to be inserted through a proximal aperture 12pa that is aligned with advancement member longitudinal axis 19al.

On page 25, please replace the paragraph starting on line 14 with the following:

Pushable member 19 has proximal and a distal portion 19p and 19d. Proximal portion 19p can have an inward convex curve 19c or indentation 19i to facilitate force application and advancement by pushing tool 21. Similarly the advancements tool 21 can have a recessed or convex curved contour 21c at its proximal portion to facilitate finger manipulation. At least a portion of distal portion 19d comprise electrode 18. The proximal portion can have a significantly larger diameter 19dp relative to distal portion rendering proximal portion stiffer than distal portion. The ratio of diameters of proximal to distal portion can be in the range of 1:2 to 1:10, with corresponding ratios of column strength or stiffness. Proximal portion 19p has sufficient diameter and column strength to advance the entire length of electrode 18 into various tissue include hard fibrous tissue such. Proximal portion 19p can have a diameter in the range of 0.1 to 0.5 inches with specific embodiment of 0.2, 0.3 and 0.4 inches. The proximal portion 19p can be made of a conductive high strength metal such as 304 or 304V stainless steel or hardened tool steel. Proximal portion 19p and distal portion 19d can be an integral component or can be joined using metal working methods known in the art including soldering, brazing and welding. Advancement member 19 can be configured to be retracted by means of a spring such as a coiled spring 19g that can be positioned over distal portion 19p or otherwise coupled to advancement member 19. Spring 19g has diameter 19gd configured to fit over distal portion 19d/electrode 18 but be contained or but up against the larger diameter of proximal portion 19p. A releasable locking or clamp device 19cd can be coupled to spring 19g and advancement member to be able lock advancement member 19 and electrode position deployed. Advancement tool 21 has a proximal portion 21p and elongated portion 21e, including a distal portion 21d. Proximal portion can have a cylindrical shape configured to held and pushed with finger including a recessed proximal contour 21cp. Also all or portions of tool 21 can including a proximal portion 21p can be include an electrically insulative layer 21c to electrically isolate tool 21 from member 19. Elongated portion 21e can be a solid cylindrical shaft configured to be inserted through proximal aperture 12pa and make contact with and advance advancement member 19. Proximal portion 21p can be configured to remain outside of the housing 12 (by virtue of it having a larger diameter than proximal aperture 12a), such that the length 21e of elongated portion 21e control the penetration depth 18pd of electrode 18. Accordingly, the length 18el of elongated portion 18e can be in the range of 0.1 to 5 cm with specific embodiment of 0.5, 1.0, 1.5, 2.0, 2.5, 3.0 and 4.0 cm. All or portions of tool 21 can be made from rigid injection moldable

polymers such as polycarbonate or ABS or machined tool steel known in the art. In an embodiment tool can be thumbtack shaped with a plastic proximal portion 12p and an embedded elongated portion 21e.

On page 27, please replace the paragraph starting on line 13 with the following:

Referring to Figure 22, in a method of the invention the physician can use one or more advancement members 19 having different elongated section lengths 19e to deploy one or more selected electrodes of electrode array 18a to selectable depths to produce a volumetric pattern 5p or profile of deployed electrode 18 to correlate to a tumor mass 5" and avoid nearby critical structures so as to produce a selectable ablation volume 5av. The physician could use locking device 19cd to lock each electrode in place during energy delivery and subsequently release one or more selected electrode and then re-deploy those electrodes to a different depth for a second delivery of energy to produce a continuous ablation volume or two or more distinct ablation volumes.

On page 27, please replace the paragraph starting on line 24 with the following:

Referring to Figures 20a-20e, advancement member 16 can be advanced by a number of different mechanical, electromechanical or pneumatic means known in the art which can be coupled or integral to advancement member 16. In these and related embodiments advancement member 16 can an advancement device 16 or otherwise include an advancement device. In a preferred embodiment shown in Figure 20a, member 16 is advanced by means of a push rod or stiffened cable 16c coupled to member surface 16s and a handpiece 24 actuatable by an actuator 24" on handpiece 24 both described herein. In this and other embodiments retraction of member 16 (e.g. proximal movement) can be achieved through the use of one or more springs 16sprg, such as coil spring coupled to the proximal or distal surface of member 16 and the proximal or distal surface of housing interior 12i. When member 16 is advanced in the proximal direction spring 16sprg is stretched such that the spring now exerts a spring force on member 16 in the proximal direction. When the deployment force exerted by the push rod, servo motor, air pressure or other means described herein is removed, the spring force is sufficient to cause member 16 to be withdrawn back to its starting position and withdrawal electrodes 18 from their deployed state in tissue. In various embodiments, the spring force of the one or more springs 16sprg can be in the range of 0.1 to 5 lbs with specific embodiments of 0.25, 0.5, 0.75, 1 and 2.5 lbs. Springs 16sprg can be made from spring steel known in the art. In one embodiment



springs 16sprgs are configured to have a selectable amount of spring force achieved through the amount of compression or deflection of the spring.

On page 28, please replace the paragraph starting on line 22 with the following:

In an alternative embodiment shown in Figure 20b, member 16 can be advanced by a servo motor or solenoid 16m known in the art positioned on the interior or exterior of housing 12 and mechanically coupled to member 16. Motor 16m can include miniature motors including the types used for positioning auto-focus lenses such as those manufactured by RMB Miniature Bearings (Switzerland). Position sensors 22 such as LVDT's can be positioned on member 16 or housing interior 12id to provide information on the location of member 16 and amount of deployment of electrodes 18. In still another embodiment shown in Figure [22c]20c, member 16 can be advanced by pneumatic means such as a source of compressed air or inert gas and the like 16g fluidly coupled to housing interior 12i. Gas 16g can also be used to cool the housing 12 including surface 14, electrode 18 and tissue surface 5s. In a related embodiment, member 16 and housing interior 12i are coupled to a vacuum source 16v configured to reverse the motion of member 16 and withdrawal coupled electrodes 18. Vacuum source 16v can also be used to provide suction and adherence of contacting surface 14 to tissue surface 14 via the use of one or more suction apertures 14va positioned on surface 14. Apertures 14va can be the same as 14a. This solves the problem of achieving and maintaining good contact between contact surface 14 and tissue surface 5s (before, during and after energy delivery) as well allowing rapid release between the two. Both compressed gas source 16g and vacuum 16c can be actuable by actuator 24" which can be or otherwise electronically coupled to a control valve 24cv known in the art.

On page 29, please replace the paragraph starting on line 20 with the following:

In another embodiment shown in Figure 20d, advancement member 16 is advanced by inflatable balloon device 16ib positioned within housing interior 12i and coupled (movably or attached) to member 16. Inflation of balloon 16ib exerts sufficient force against member surface 16s (which is opposed by an equal opposite force on housing interior 12i) so as to push member 16 in a distal direction and deploy electrodes 18. Balloon device 16ib can be coupled to an inflation/deflation device known in the art or to compressed gas source 16g and/or vacuum source 16c. In an embodiment balloon device 16ib can be mechanically coupled, directly attached to or integral with member 16 and housing interior 12i such that

the inflation/deflation of balloon 16ib directly advances and retracts member 16 so as to deploy and retract electrodes 18.

On page 30, please replace the paragraph starting on line 13 with the following:

Referring to Figure 20e, in an embodiment advancement member 16 can be an advancement device 16 and can comprise a cam 16c known in the art whose motion serves to advance energy delivery device 18 through contact of the cam surface 16s with the proximal end 18p or other portion the energy delivery device. Suitable cams include disk cams, translational cams or cylindrical cams configured to operate within housing 12 using rotary, axial or lateral motion and a suitable cam follower 16cf which can be coupled to energy delivery device 18 or can be energy delivery device 18 itself. In another embodiment the advancement device 16 can be movably or detachably coupled to electrodes 18 including rotational, pivotal and reciprocal couplings.

Turning now to a discussion of electrodes and electrode configurations, in various embodiments electrodes 18 can have a variety of shapes and geometries. Referring to Figures 23a-23h, example shapes and geometries can include, but are not limited to, ring-like, ball, hemispherical, cylindrical, conical, needle-like and combinations thereof. Referring to Figure 24, in an embodiment electrode 18 can be a needle with sufficient sharpness to penetrate tissue including fibrous tissue including, encapsulated tumors cartilage and bone. The distal end 18de of electrode 18 can have a cut angle 68 that ranges from 1 to 60°, with preferred ranges of at least 25° or, at least 30° and specific embodiment of 25° and 30°. The surface of electrode 18 can be smooth or textured and concave or convex. The conductive surface area 18s of electrode 18 can range from 0.05 mm<sup>2</sup> to 100 cm<sup>2</sup>. Referring to Figure 25, electrode 18 can also be configured to be flexible and or deflectable having one or more radii of curvature 70 which can exceed 180° of curvature. In use, electrode 18 can be positioned to heat, necrose or ablate any selected target tissue volume 5'. A radiopaque marker 11 can be coated on electrodes 18 for visualization purposes.

On page 33, please replace the paragraph starting on line 3 with the following:

Referring now to Figures 30a and 30b, electrode 18 can include one or more lumens 72 (which can be contiguous with or the same as lumen 13) coupled to a plurality of fluid distribution ports 23 (which can be apertures 23) from which a variety of fluids 27 can be introduced, including conductivity enhancing fluids, electrolytic solutions, saline solutions,

cooling fluids, cryogenic fluids, gases, chemotherapeutic agents, medicaments, gene therapy agents, photo-therapeutic agents, contrast agents, infusion media and combinations thereof. This is accomplished by having ports or apertures 23 that are fluidly coupled to one or more lumens 72 coupled to lumens 13 in turn coupled to fluid reservoir 30 and/or fluid delivery device 28.

On page 36, please replace the paragraph starting on line 8 with the following:

Turning now to a discussion of power supplies and power delivery, when power supply 20 is a RF source it produces RF energy delivered to tissue through RF electrode 18. RF energy flowing through tissue causes heating of the tissue due to absorption of the RF energy by the tissue and ohmic heating due to electrical resistance of the tissue. The heating causes tissue temperature to rise sufficiently to cause cell injury and death particularly for temperatures in excess of 50-55° C. Increased amounts of power will resultant in higher temperature and greater magnitude of cell death it is desirable to be able to deliver a range of RF power levels depending upon a variety of parameters include but not limited to tumor size, tissue type, tumor location and amount of tumor vascularization. Accordingly in varying embodiments, RF power supply 20 can be figured to deliver between 5 to 200 watts, preferably 5 to 100, and still more preferably 5 to 50 watts of electromagnetic energy is to the electrodes of energy delivery device 18 without impeding out. This can be accomplished through the use of cooling solutions and methods described herein as well as the use of power duty cycles to allow for a certain amount of thermal dissipation in and around electrodes 18.

On page 45, please replace the paragraph starting on line 1 with the following:

The use of forcep device 24f allows the physician to not only shape the contact surface 14 to the tissue surface but also to apply a selectable amount of pressure to the tissue surface to do one or more of the following: (i) stabilize the housing on the tissue surface; (ii) at least partially immobilize the target tissue site; and (iii) at least partially stop the flow of blood to the target tissue through the application of direct pressure including onto a selected vessel or vasculature.

On page 46, please replace the paragraph starting on line 24 with the following:

In a preferred embodiment, in their non deployed state electrodes 18 are completely contained or recessed within housing 12, particular tissue penetrating distal end 18de in the

non deployed state and then subsequently during electrode retraction. This configuration provides the benefit of a safety feature to prevent accidental stick injury to medical personnel and the patient. This is achieved by having electrode length 18l be less than housing length 12l. In its fully deployed state electrode has deployed portion 18dp protruding distally out of housing 12 and into tissue and a non-deployed portion 18ndp that is contained in housing 12. In various embodiments, electrode 18 has a deployed length 18dl in the range of 0.25 to 20cm with specific embodiments of 1.5 cm, 2.5, 4, 5 and 10 cm[s] in order to achieve a penetration depth 18pd roughly corresponding to these amounts. In an embodiment, the non-deployed length can be in the range of 0.25 to 3 cm. At the same time, the housing 12 has sufficient length to allow complete withdrawal of electrodes 18 into the housing to prevent accidental stick injury both to the patient and medical personnel during positioning and manipulation of the housing and apparatus. Thus in various embodiments, the length of housing 12 can range of 0.5 cm to 9 cm with specific embodiments of 2.5, 5.0 and 7.5 cm. The actual lengths of electrode 18 depends on the location of tissue site 5' to be ablated, its distance from the site, its accessibility as well as whether or not the physician chooses a open surgical procedure or a percutaneous, or other minimally invasive procedure.

On page 53, please replace the paragraph starting on line 25 with the following:

Referring to Figure 45, all or portions of tissue surface 14 can be a conductive surface 14con configured as the either the energy delivery electrode or the return electrode. This can be accomplished by fabricating surface 14 from conductive materials, coatings, or from porous material configured to contain and or weep a conductive fluid film both configurations described herein. In various embodiments conductive surface 14con can be configured as a monopolar positive electrode, a monopolar return electrode or bipolar electrode. Switching between these different modes can be accomplished through the use of a switching device 46 such as a multiplexing device or programmably switching device coupled to one or more conductive surface 14con, electrodes 18 and power supply 20.

On page 54, please replace the paragraph starting on line 11 with the following:

Referring to Figure 46, in a related embodiment conductive surface 14con can comprise one or more conductive areas 14cona which can each be individually controlled to an on/off state using coupled to switching device 46. The use of switching device 46 allows the user to dynamically increase or decrease the conductive area 14con of contact surface 14

to do one or more of the following: (i) adjust the area of conductive surface 14 con as an energy delivery electrode or return electrode to compensate for changes in tissue impedance; (ii) adjust the area of tissue heated; (iii) adjust the rate of tissue heating; and (iv) adjust the area of area of conductive surface as a return electrode in order to prevent thermal damage to non-target tissue including coagulation of blood vessels such as the hepatic vein.

On page 55, please replace the paragraph starting on line 3 with the following:

Referring to Figure 47, in related embodiments employing a conductive contact surface 14con as an electrode, one or more electrodes 18 can be selected as the positive electrode 18p, using switching device 46 and so create a selectable composite vector(s) 18v of current or energy into target tissue 5' having a selectable direction and magnitude. The selection and configuration of electrodes 18 to produce a given vector can be controlled by logic resources 350 coupled to switching device 46 which can be a multiplexing device. The vector 18v can be in the volume 5ve defined by deployed electrodes 18, or the volume 5vec deployed electrodes 18 and conductive surface 14con. In use, this approach allows the physician to more precisely control or titrate the delivery of RF or others electromagnetic energy to yield higher current densities and hence temperatures in selected portions of the target tissue volume and lower current densities in other selected areas. This configuration in turn provides benefit of providing a higher degree of cell necrosis/ablation with a lower risk of tissue desiccation and excessive impedance build up.

On page 55, please replace the paragraph starting on line 19 with the following:

Referring to Figure 48, in another embodiment one or more electrodes 18 and/or conductive surface 14 con can be configured to produce a phased array of RF electrode 18pa to obtain a zone or area of constructive signal interference 5ci within target tissue volume 5' under tissue surface 5s and hence an enhanced thermal effect with more rapid tissue heating and necrosis. Phased array embodiments can include use of conductive surface 14con as either a positive or electrode 18p, 18r. Electrodes 18 and/or conductive surface 14con can be coupled to a controller 339 described herein having logic resources (e.g. a microprocessor) 350 that adjusts the feedback signal, with a gradient search or matrix inversion algorithm known in the art, to provide a uniform electric field radiation into the target tissue site 5ci.

On page 56, please replace the paragraph starting on line 5 with the following:

Depending upon the location of the tumor it may be advantageous to operate in a bipolar mode so as not to have the return electrical current flow through a narrowed or small portion of the liver where the tissue impedance can be great enough to cause a temperature increase sufficient to coagulate or damage the hepatic vein or other hepatic vasculature. Accordingly, referring to Figures 50a and 50b, in an embodiment impedance measurement circuitry and/or controller/logic resources 339/350 (coupled to power source 20) can be configured to determine if the return path impedance is sufficient to cause heating anywhere along the return path and automatically switch into a bipolar mode either prior to energy delivery or once such impedance or resulting temperature exceeds a preselected threshold. In a related embodiment, thermal, flow and coagulation sensors 22 can be positioned in the hepatic vasculature within target site 5' or nearby tissue. Sensors 22 can monitor both the temperature of the hepatic vasculature as well as monitor blood flow rates there through the hepatic vasculature. Again sensors 22 are coupled to logic resources which switch from a monopolar to a bipolar mode, shut off or otherwise attenuate the delivery of power to target site 5' when: (i) the tissue temperature exceeds an absolute threshold or a rate of increase; (ii) the blood flow rate falls below an absolute threshold or a rate of decrease; or (iii) a combination of items (i) and (ii). In these and related embodiments, sensors 22 can be positioned on electrode 18 or passive non energy delivering members which can be positioned at varying distances from energy delivery devices 18 so as to be to passively monitor tissue temperatures at selected distances from electrode 18. Sensors 22 can be electronically coupled to logic resource in turn coupled to power source 20. Such resources can include microprocessors containing embedded modules or software programs. Such microprocessors can include an Intel® Pentium® III chip or a PowerPC® chip manufactured by the Motorola Corporation. Such resource can also contained embedded control modules that include process control algorithms known in the art such as PID algorithms. The switching between monopolar to bipolar modes can be achieved by the use of switching circuitry 20s including multiplexer devices (including a densely packed wavelength multiplexor) coupled to one or more electrodes 18 as wells as return electrode 18r and tissue contact surface 14 including conductive portions 14con. Switching to bipolar mode also serves to keep RF induced heating closer to tissue surface 5s thus preventing the unwanted heating of deeper tissue containing healthy tissue and/or thermally sensitive structures. Thus in use, embodiments having the ability to have feedback control to switch

between monopolar and bipolar modes present the advantage of more refined and faster control over the depth of tissue heating to prevent thermal injury of underlying healthy/sensitive tissue without having to reposition the electrodes.

On page 57, please replace the paragraph starting on line 22 with the following:

Referring to Figures 50a, 50b, and 51, in another embodiment of the invention surface treatment apparatus 10 can comprise a collapsible strut apparatus 110 configured to be coupled to power source 20. Collapsible apparatus 110 can be configured to positionable within an endoscopic or a surgical introducing device 111 such as an endoscope, trocar and the like. Collapsible apparatus 110 has a collapsed or non deployed position shown in 50a and a deployed position shown in Figure 50b. Collapsible apparatus 110 includes a central elongated or shaft member 112 having a distal section 112ds including a end 112de. A needle electrode 118n can be fixedly or movably attached to tip 112de. Also shaft member 112 can include a lumen 112l which can be configured to allow the advancement of a rigid or a flexible advancement member 116. Advancement member 116 can be flexible or rigid and can be guide wire, hypotube, or polymer shaft all having sufficient column strength to advance a distally coupled needle into tissue. Advancement member 116 can be coupled to a needle electrode 118n to allow its advancement into tissue.

On page 58, please replace the paragraph starting on line 12 with the following:

A movable proximal hub 120 is slidably positioned over shaft 112 and is configured to slides over distal section 112ds and can be releasably locked in position in position using a first locking device 120l which can be a latch, locking nut or clamp known in the art. A distal hub 126 is positioned over distal end 112de and preferably is fixedly mounted. However the longitudinal position of hub 126 with respect to shaft longitudinal axis 112al can be adjusted using a second locking device 126l. Alternatively, in embodiment shown in Figure 51, distal hub 126 can be movable and proximal hub 120 can be fixed. Also, proximal hub 120 can comprise an overtube 120ot that is slidably positioned over shaft 112. Both of hubs 120 and 126 can be configured to be advanced and retracted by a coupled guidewire or other mechanical linkage known in the art. In an embodiment one, or both of hubs 120 and 126 can include a flange 121f or 126f that enables one or both hubs to be pushed (advanced) and pulled back via means of either stiffened guide wires mechanically coupled (e.g. by welding) to either flange or a hollow advancement tube member 130 that is coupled to or otherwise pushes up against either flange. In yet another embodiment either

flange 121f or 126 f can be configured to act as pneumatic or fluidic seal against the lumen of an overlying introducer 111 such that either hub can be and retracted so as to deploy and retract electrodes 118 pneumatically or hydraulically using an air or fluid pressure source 140 known in the medical device arts. An example of air pressure source includes a tank of compressed gas and a fluid pressure source includes a syringe pump.

On page 63, please replace the paragraph starting on line 17 with the following:

Referring now to Figures 53a and 53b, in an alternative embodiment expansion device 129 can comprise an expandable balloon device known in the art such as a dilatation balloon known in the art. Guide tubes 128 can be distributed along a perimeter 129p or a portion thereof of balloon device 128. Balloon device 129 can be coupled to guide tubes 128 using adhesive bonding and other polymer bonding methods known in the art (or alternatively balloon device 129 and guide tubes 128 can be integrally formed). Balloon 129 is expanded to a selectable diameter to achieve a selected spacing or diameter 134d of a geometric shape whose perimeter is defined by deployed guide tubes 128. The shape or diameter of this shape in turn defines the collective shape or pattern 134 of deployed electrodes 118. The degree of inflation of balloon 129 can be used to match the diameter of deployed shape 134 to that of the tumor mass 5" or selected target tissue site 5'.

On page 65, please replace the paragraph starting on line 3 with the following:

In an alternative embodiment shown in Figure 53b a sizing or restraining member 131 can be disposed over balloon 129 and used to control the maximum inflated diameter 129d of balloon 129 as well as the inflated shape of balloon 129. The sizing member can be coupled to the proximal and distal portions of balloon 129 and can comprise a DACRON sheath or other collapsible yet substantially non-compliant material known in the biomedical material arts including polyesters, PET and the like.

On page 69, please replace the paragraph starting on line 3 with the following:

Referring now to Figure 54, all or portions of feedback control system 329 are illustrated. Current delivered through RF electrodes 314 and 316 (also called primary and secondary RF electrodes/antennas 314 and 316) is measured by a current sensor 330. Voltage is measured by voltage sensor 332. Impedance and power are then calculated at power and impedance calculation device 334. These values can then be displayed at a user interface and display 336. Signals representative of power and impedance values are received by controller 338 which can be a microprocessor 338.



On page 71, please replace the paragraph starting on line 21 with the following:

Referring now to Figure 55, current sensor 330 and voltage sensor 332 are connected to the input of an analog amplifier 344. Analog amplifier 344 can be a conventional differential amplifier circuit for use with sensors 324. The output of analog amplifier 344 is sequentially connected by an analog multiplexer 346 to the input of A/D converter 348. The output of analog amplifier 344 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D converter 348 to a microprocessor 350. Microprocessor 350 may be Model No. 68HCII available from Motorola. However, it will be appreciated that any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

**REMARKS**

Entry of the above amendments prior to examination is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims. The attached pages are captioned "**Version with Markings to Show Changes Made.**"

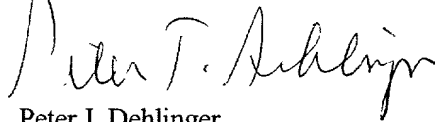
A. Amendments to the Specification

The specification has been amended to correct drawing numbering. The specification has further been amended to describe figures 23g-23h, 45, and 49a-49b. The specification has further been amended to correct obvious typographical and grammatical errors.

The amendments to the specification add no new matter.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4401.

Respectfully submitted,



Peter J. Dehlinger  
Registration No. 28,006

Date: 6-18-02

**Correspondence Address:**

Customer No. 22918

**Version with Markings to Show Changes Made**

page 6, paragraph starting on line 20

Figures 9a-9b [is a]are bottom surface views illustrating an embodiment of a bendable tissue contacting surface with articulated sections.

page 7, paragraph starting on line 8

Figures 15a-15[c]d are lateral views illustrating various alignments for the aperture and electrodes of the embodiment in Figure 7.

page 7, paragraph starting on line 18

Figure [20]21 is a lateral view illustrating an embodiment of an advancement member comprising one or more pushable advancement members with coupled electrodes.

page 7, paragraph starting on line 21

Figures [21]22a-22e [is a]are perspective views illustrating the use of the embodiment of the apparatus of Figure 13.

page 7, paragraph starting on line 23

Figure [22a]20a is a lateral view illustrating an embodiment utilizing a push rod to advance the advancement member as well as the use of springs for retracting the advancement member.

page 8, paragraph starting on line 1

Figure [22b]20b is a lateral view illustrating an embodiment utilizing a servomotor or solenoid to advance the advancing the advancement member.

page 8, paragraph starting on line 4

Figure [22c]20c is a lateral view illustrating an embodiment utilizing pneumatic means to advance the advancing the advancement member as well as the use of vacuum source.

page 8, paragraph starting on line 7

Figure [22d]20d is a lateral view illustrating an embodiment utilizing an inflatable balloon to advance the advancing the advancement member.

page 8, paragraph starting on line 9

Figure [22e]22e is a lateral view illustrating an embodiment wherein the advancement member includes a cam to advance the advancement member.

page 8, paragraph starting on line 12

Figures 23a-23[f]h are lateral views illustrating various configurations of the electrode including ring-like, ball, hemispherical, cylindrical, conical and needle-like.

page 11, paragraph starting on line 4

[Figure 46 is a schematic view illustrating an embodiment of the tissue contact surface having a conductive portion employed in monopolar and bipolar modes.]

page 11, paragraph starting on line 7

Figure [47]46 is a schematic view illustrating an embodiment of the tissue contact surface having multiple conductive portions.

page 11, paragraph starting on line 9

Figure [48]47 is a schematic view illustrating an embodiment of a conductive tissue contact surface used to generate and control a current/energy vector within the target tissue volume.

page 11, paragraph starting on line 12

Figure [49]48 is a schematic view illustrating an embodiment of the surface treatment apparatus having a phased array of electrodes.

page 11, paragraph starting on line 14

Figure [50a]49a is a flow chart illustrating an embodiment of a method of the invention utilizing an algorithm to switch between monopolar and bipolar modes based on measurement of tissue impedance.

page 11, paragraph starting on line 17

Figure [50b]49b is schematic view of an embodiment of an apparatus for performing the method of Figure [50a]49a.

page 11, paragraph starting on line 19

Figures [51a and 51b]50a and 50b are lateral views illustrating embodiments of a collapsible strut surface treatment apparatus in a non-deployed and deployed state having a fixed distal hub.

page 11, paragraph starting on line 22

Figure [52]51 is a lateral view illustrating an alternative embodiment of the collapsible strut surface treatment apparatus having a movable distal hub.

page 11, paragraph starting on line 25

Figure [53]52 is a lateral view illustrating the use of the embodiment of Figure [51b]50b or Figure [52]51 to produce multiple ablation volumes.

page 12, paragraph starting on line 1

Figure [54a]53a is a lateral view illustrating an embodiment of a collapsible surface treatment apparatus utilizing an expandable balloon device.

page 12, paragraph starting on line 4

Figure [54b]53b is a lateral view illustrating an embodiment of a collapsible surface treatment apparatus utilizing an expandable balloon device with a restraining member.

page 12, paragraph starting on line 7

Figure [55]54 is a block diagram illustrating a controller, power source, power circuits and other electronic components used with an embodiment of a control system other embodiments of the invention.

page 12, paragraph starting on line 10

Figure [56]55 is a block diagram illustrating an analog amplifier, analog multiplexer and microprocessor used with an embodiment of a control system other embodiments of the invention.

page 13, paragraph starting on line 6

Also, various embodiments are configured to treat not only accessible anterior portions of the liver but also posterior portions and/or portions obstructed by overlying or adjacent tissue and other organs and tissue. This capability is achieved through the use of components with sufficient flexibility and resiliency to bend, curve around or conform to tissue and anatomical structures including organs, bone and [vasulature]vasculature. Components of the apparatus of the invention having this flexibility can include the handpiece, housing and tissue contact surface described in detail herein. This flexibility enables the apparatus to not only be readily manipulated and positioned in at least partially obstructed tissue but also to deliver energy, fluids and apply pressure to and on obstructed or otherwise difficult to reach target tissue sites.

page 17, paragraph starting on line 23

Turning now to a discussion of the tissue contacting surface 14 (also called tissue contact surface 14), this component can have a variety of shapes including but not limited to circular, oval, rectangular, square and combinations thereof. Referring now to Figures 5a to 5e, contact surface 14 can have a variety of contours 14ctr including curved contours including convex or concave curved contours and combinations thereof. Additionally, [ithe]the edges 14e of contacting portion 14 can be tapered 14t or radiused 14r.

page 17, paragraph starting on line 1

In a related embodiment, coating 12c can be a non-stick or lubricous coating 12lc configured to keep surface 14 or other portion of housing 12 or energy delivery 18 from sticking to tissue surface 5s before during or after ablation. This solves the problem of coagulated or burnt tissue [unwantly]undesirably sticking to surface 14 preventing its removal and/or causing unwanted tearing and other trauma to tissue surface 5s or tissue 5. Such coatings can include PTFE, TEFLON and other fluoro-carbon polymers, silicones, paralene and other low surface tension non-stick coatings known in the art.

page 19, paragraph starting on line 25

Referring to Figures 10-14, in various embodiments, all or a portion of conformable surface 14 can be constructed from a porous material [fluidically]fluidly coupled to a fluid source and/or fluid delivery device described herein. In an embodiment shown in Figure 10, a porous portion or section 14p of surface 14 is configured to deliver a fluid film 14ff to

target tissue surface 5s. Porous portion 14p can be made from a porous membrane or other porous material. Suitable porous materials can include but are not limited to foam, foam rubber, polyurethane foam, cellulose and woven or knitted DACRON, knitted polyester, continuous filament polyester, polyester-cellulose, rayon, polyamide, polyurethane, polyethylene and the like. The delivery of a fluid film in this manner can be configured to perform one or more of the following functions: (i) produce a virtual fluid electrode adjacent or in the tissue surface to uniformly deliver RF energy to the selected tissue surface and underlying tissue when using a conductive solution; (ii) produce a virtual and electrically uniform ground pad electrode on the selected tissue surface to act as a return path for RF energy when using a conductive solution; and (iii) provide cooling over the selected tissue surface when a cooling solution is used which can also be a conductive solution. Porous surface 14p can have selectable and/or variable amounts of porosity. In one embodiment, porous portion 14p has uniform porosity and thickness so as to be able to achieve a substantially uniform delivery of fluid over porous portion surface 14ps. In another embodiment the porosity is varied over portion 14p including surface 14ps to produce varying amounts of fluid flow. For example, higher porosity on the perimeter to produce greater flows on the perimeter or edges of section 14p or alternatively greater porosities in the center portion. Also the porosity of section 14p can be controlled to retain fluid within the interior of section 14p in order to have section 14p act as a virtual or enhanced electrode 40 (described here in) including a virtual flexible electrode. Alternatively, one or more RF electrodes, such as plate or ring shaped RF electrodes 18, may be positioned within section 14p to both cool the electrode and conduct RF energy to section 14p to allow section 14p to act as an RF electrode to deliver RF energy to tissue surface 5s and underlying tissue.

page 19, paragraph starting on line 8

Referring to Figures 8 and 9a-9b, in other embodiments surface 14 can comprise one or more bendable sections 14b. In an embodiment shown in Figure 8, bendable sections 14b can include hinges 14h' to allow surface 14 to be moved and shaped by the physician prior to or during application of surface 14 to the target tissue surface. The hinges 14h' used can include those known in the art including spring loaded hinges giving the bendable sections 14b shape resilience. Hinges 14' can also include bearings, roller bearings, and miniature bearings such as those manufactured by RMB Miniature Bearings (Biel-Bienne, Switzerland). In a related embodiment shown in Figures 9a-9b, all or portion of surface 14

can include articulated sections 14as fabricated using known methods of articulated construction such as use of corrugated sections made using molding methods known in the art. Articulated sections 14as have a sufficient number of articulations 14as' to allow robust movement of surface 14 in one or more directions. Articulated sections 14as can be configured to bend or deflect with a selectable amount of applied force which can be in the range of 0.01 to 2 lbs with specific embodiment of 0.05, 0.1, 0.25, 0.5 and 1[bl]lb of force.

page 22, paragraph starting on line 15

Referring to Figures 15a-15[c]d, in various embodiments aperture 14a and electrode 18 can have different alignments including but not limited to the following: (i) aperture locus 14ac aligned with the centerline axis 18acl of electrode 18; (ii) aperture longitudinal axis 14aal substantially aligned with the electrode longitudinal axis 18al; and (iii) electrode longitudinal axis 18al substantially perpendicular to aperture plane 14ap.

page 25, paragraph starting on line 14

In an embodiment shown in Figure [20]21, advancement member 16 comprises one or more individual pushable advancement members 19 each coupled to or including an individual electrode 18 that is aligned with a corresponding apertures 14a so as to exit from aperture 14a. Pushable advancement members 19 can in turn be configured to be mechanically advanced by means of an advancement tool 21 that is configured to be inserted through a proximal aperture 12pa that is aligned with advancement member longitudinal axis 19al.

page 25, paragraph starting on line 14

Pushable member 19 has proximal and a distal portion 19p and 19d. Proximal portion 19p can have an inward convex curve 19c or indentation 19i to facilitate force application and advancement by pushing tool 21. Similarly the advancements tool 21 can have a recessed or convex curved contour 21c at its proximal portion to facilitate finger manipulation. At least a portion of distal portion 19d comprise electrode 18. The proximal portion can have a significantly larger diameter 19dp relative to distal portion rendering proximal portion stiffer than distal portion. The ratio of diameters of proximal to distal portion can be in the range of 1:2 to 1:10, with corresponding ratios of column strength or stiffness. Proximal portion 19p has sufficient diameter and column strength to advance the entire length of electrode 18 into various tissue include hard fibrous tissue such. Proximal portion 19p can have a diameter in the range of 0.1 to 0.5 inches with specific embodiment



of 0.2, 0.3 and 0.4 inches. The proximal portion 19p can be made of a conductive high strength metal such as 304 or 304V stainless steel or hardened tool steel. Proximal portion 19p and distal portion 19d can be an integral component or can be joined using metal working methods known in the art including soldering, brazing and welding. Advancement member 19 can be configured to be retracted by means of a spring such as a coiled spring 19g that can be positioned over distal portion 19p or otherwise coupled to advancement member 19. Spring 19g has diameter 19gd configured to fit over distal portion 19d/electrode 18 but be contained or but up against the larger diameter of proximal portion 19p. A releasable locking or clamp device 19cd can be coupled to spring 19g and advancement member to be able lock advancement member 19 and electrode position deployed. Advancement tool 21 has a proximal portion 21p and elongated portion 21e, including a distal portion 21d. Proximal portion can have a cylindrical shape configured to held and pushed with finger including a recessed proximal contour 21cp. Also all or portions of tool 21 can including a proximal portion 21p can be include an electrically insulative layer 21c to electrically isolate tool 21 from member 19. Elongated portion 21e can be a solid cylindrical shaft configured to be inserted through proximal aperture 12pa and make contact with and advance advancement member 19. Proximal portion 21p can be configured to remain outside of the housing 12 (by virtue of it having a larger diameter than proximal aperture 12a), such that the length 21e of elongated portion 21e control the penetration depth 18pd of electrode 18. Accordingly, the length 18el of elongated portion 18e can be in the range of 0.1 to 5 cm with specific embodiment of 0.5, 1.0, 1.5, 2.0, 2.5, 3.0 and 4.0 cm[s]. All or portions of tool 21 can be made from rigid injection moldable polymers such as polycarbonate or ABS or machined tool steel known in the art. In an embodiment tool can be thumbtack shaped with a plastic proximal portion 12p and an embedded elongated portion 21e.

page 27, paragraph starting on line 13

Referring to Figure [21]22, in a method of the invention the physician can use one or more advancement members 19 having different elongated section lengths 19e to deploy one or more selected electrodes of electrode array 18a to selectable depths to produce a volumetric pattern 5p or profile of deployed electrode 18 to correlate to a tumor mass 5" and avoid nearby critical structures so as to produce a selectable ablation volume 5av. The physician could use locking device 19cd to lock each electrode in place during energy delivery and subsequently release one or more selected electrode and then re-deploy those

electrodes to a different depth for a second delivery of energy to produce a continuous ablation volume or two or more distinct ablation volumes.

page 27, paragraph starting on line 24

Referring to Figures [22a-22e]20a-20e, advancement member 16 can be advanced by a number of different mechanical, electromechanical or pneumatic means known in the art which can be coupled or integral to advancement member 16. In these and related embodiments advancement member 16 can an advancement device 16 or otherwise include an advancement device. In a preferred embodiment shown in Figure [22a]20a, member 16 is advanced by means of a push rod or stiffened cable 16c coupled to member surface 16s and a handpiece 24 actuable by an actuator 24” on handpiece 24 both described herein. In this and other embodiments retraction of member 16 (e.g. proximal movement) can be achieved through the use of one or more springs 16sprg, such as coil spring coupled to the proximal or distal surface of member 16 and the proximal or distal surface of housing interior 12i. When member 16 is advanced in the proximal direction spring 16sprg is stretched such that the spring now exerts a spring force on member 16 in the proximal direction. When the deployment force exerted by the push rod, servo motor, air pressure or other means described herein is removed, the spring force is sufficient to cause member 16 to be withdrawn back to its starting position and withdrawal electrodes 18 from their deployed state in tissue. In various embodiments, the spring force of the one or more springs 16sprg can be in the range of 0.1 to 5 lbs with specific embodiments of 0.25, 0.5, 0.75, 1 and 2.5 lbs. Springs 16sprg can be made from spring steel known in the art. In one embodiment springs 16sprgs are configured to have a selectable amount of spring force achieved through the amount of compression or deflection of the spring.

page 28, paragraph starting on line 22

In an alternative embodiment shown in Figure [22b]20b, member 16 can be advanced by a servo motor or solenoid 16m known in the art positioned on the interior or exterior of housing 12 and mechanical coupled to member 16. Motor 16m can include miniature motors including the types used for positioning auto-focus lenses such as those manufactured by RMB Miniature Bearings (Switzerland). Position sensors 22 such as LVDT's can be positioned on member 16 or housing interior 12id to provide information on the location of member 16 and amount of deployment of electrodes 18. In still another embodiment shown in Figure [22c]20c, member 16 can be advanced by pneumatic means

such as a source of compressed air or inert gas and the like 16g [fluidically]fluidly coupled to housing interior 12i. Gas 16g can also be used to cool the housing 12 including surface 14, electrode 18 and tissue surface 5s. In a related embodiment, member 16 and housing interior 12i are coupled to a vacuum source 16v configured to reverse the motion of member 16 and withdrawal coupled electrodes 18. Vacuum source 16v can also be used to provide suction and adherence of contacting surface 14 to tissue surface 14 via the use of one or more suction apertures 14va positioned on surface 14. Apertures 14va can be the same as 14a. This solves the problem of achieving and maintaining good contact between contact surface 14 and tissue surface 5s (before, during and after energy delivery) as well allowing rapid release between the two. Both compressed gas source 16g and vacuum 16c can be actuable by actuator 24" which can be or otherwise electronically coupled to a control valve 24cv known in the art.

page 29, paragraph starting on line 20

In another embodiment shown in Figure [22d]20d, advancement member 16 is advanced by inflatable balloon device 16ib positioned within housing interior 12i and coupled (movably or attached) to member 16. Inflation of balloon 16ib exert sufficient force against member surface 16s (which is opposed by an equal opposite force on housing interior 12i) so as to push member 16 in a distal direction and deploy electrodes 18. Balloon device 16ib can be coupled to an inflation/deflation device known in the art or to compressed gas source 16g and/or vacuum source 16c. In an embodiment balloon device 16ib can be mechanically coupled, directly attached to or integral with member 16 and housing interior 12i such that the inflation/deflation of balloon 16ib directly advances and retracts member 16 so as to deploy and retract electrodes 18.

page 30, paragraph starting on line 13

Referring to Figure [22e]20e, in an embodiment advancement member 16 can be an advancement device 16 and can comprise a cam 16c known in the art whose motion serves to advance energy delivery device 18 through contact of the cam surface 16s with the proximal end 18p or other portion the energy delivery device. Suitable cams include disk cams, translational cams or cylindrical cams configured to operate within housing 12 using rotary, axial or lateral motion and a suitable cam follower 16cf which can be coupled to energy delivery device 18 or can be energy delivery device 18 itself. In another

embodiment the advancement device 16 can be movably or detachably coupled to electrodes 18 including rotational, pivotal and reciprocal couplings.

Turning now to a discussion of electrodes and electrode configurations, in various embodiments electrodes 18 can have a variety of shapes and geometries. Referring to Figures 23a-23[f]h, example shapes and geometries can include, but are not limited to, ring-like, ball, hemispherical, cylindrical, conical, needle-like and combinations thereof. Referring to Figure 24, in an embodiment electrode 18 can be a needle with sufficient sharpness to penetrate tissue including fibrous tissue including, encapsulated tumors cartilage and bone. The distal end 18de of electrode 18 can have a cut angle 68 that ranges from 1 to 60 °, with preferred ranges of at least 25° or, at least 30° and specific embodiment of 25° and 30°. The surface of electrode 18 can be smooth or textured and concave or convex. The conductive surface area 18s of electrode 18 can range from 0.05 mm<sup>2</sup> to 100 cm<sup>2</sup>. Referring to Figure 25, electrode 18 can also be configured to be flexible and or deflectable having one or more radii of curvature 70 which can exceed 180° of curvature. In use, electrode 18 can be positioned to heat, necrose or ablate any selected target tissue volume 5'. A radiopaque marker 11 can be coated on electrodes 18 for visualization purposes.

page 33, paragraph starting on line 3

Referring now to Figures 30a and 30b, electrode 18 can include one or more lumens 72 (which can be contiguous with or the same as lumen 13) coupled to a plurality of fluid distribution ports 23 (which can be apertures 23) from which a variety of fluids 27 can be introduced, including conductivity enhancing fluids, electrolytic solutions, saline solutions, cooling fluids, cryogenic fluids, gases, chemotherapeutic agents, medicaments, gene therapy agents, photo-therapeutic agents, contrast agents, infusion media and combinations thereof. This is accomplished by having ports or apertures 23 that are [fluidically]fluidly coupled to one or more lumens 72 coupled to lumens 13 in turn coupled to fluid reservoir 30 and/or fluid delivery device 28.

page 36, paragraph starting on line 8

Turning now to a discussion of power supplies and power delivery, when power supply 20 is a RF source it produces RF energy delivered to tissue through RF electrode 18. RF energy flowing through tissue causes heating of the tissue due to absorption of the RF

energy by the tissue and ohmic heating due to electrical resistance of the tissue. The heating causes tissue temperature to rise sufficiently to cause cell injury and death particularly for temperatures in excess of 50-55° C. Increased amounts of power will result in higher temperature and greater magnitude of cell death it is desirable to be able to deliver a range of RF power levels depending upon a variety of parameters include but not limited to tumor size, tissue type, tumor location and amount of tumor vascularization. Accordingly in varying embodiments, RF power supply 20 can be figured to deliver between 5 to 200 watts, preferably 5 to 100, and still more preferably 5 to 50 watts of electromagnetic energy is to the electrodes of energy delivery device 18 without impeding out. This can be accomplished through the use of cooling solutions and methods described herein as well as the use of power duty cycles to allow for a certain amount of thermal dissipation in and around electrodes 18.

page 45, paragraph starting on line 1

The use of forcep device 24f allows the physician to not only shape the contact surface 14 to the tissue surface but also to apply a selectable amount of pressure to the tissue surface to do one or more of the following: (i) stabilize the housing on the tissue surface; (ii) at least partially immobilize the target tissue site; and (iii) at least partially stop the flow of blood to the target tissue through the application of direct pressure including onto a selected vessel or [vasculature]vasculature.

page 46, paragraph starting on line 24

In a preferred embodiment, in their non deployed state electrodes 18 are completely contained or recessed within housing 12, particular tissue penetrating distal end 18de in the non deployed state and then subsequently during electrode retraction. This configuration provides the benefit of a safety feature to prevent accidental stick injury to medical personnel and the patient. This is achieved by having electrode length 18l be less than housing length 12l. In its fully deployed state electrode has deployed portion 18dp protruding distally out of housing 12 and into tissue and a non-deployed portion 18ndp that is contained in housing 12. In various embodiments, electrode 18 has a deployed length 18dl in the range of 0.25 to 20cm with specific embodiments of 1.5 cm, 2.5, 4, 5 and 10 cm[s] in order to achieve a penetration depth 18pd roughly corresponding to these amounts. In an embodiment, the non-deployed length can be in the range of 0.25 to 3 cm[s]. At the

same time, the housing 12 has sufficient length to allow complete withdrawal of electrodes 18 into the housing to prevent accidental stick injury both to the patient and medical personnel during positioning and manipulation of the housing and apparatus. Thus in various embodiments, the length of housing 12 can range of 0.5 cm[s] to 9 cm[s] with specific embodiments of 2.5, 5.0 and 7.5 cm[s]. The actual lengths of electrode 18 depends on the location of tissue site 5' to be ablated, its distance from the site, its accessibility as well as whether or not the physician chooses a open surgical procedure or a percutaneous, or other minimally invasive procedure.

page 53, paragraph starting on line 25

Referring to Figure [46]45, all or portions of tissue surface 14 can be a conductive surface 14con configured as the either the energy delivery electrode or the return electrode. This can be accomplished by fabricating surface 14 from conductive materials, coatings, or from porous material configured to contain and or weep a conductive fluid film both configurations described herein. In various embodiments conductive surface 14con can be configured as a monopolar positive electrode, a monopolar return electrode or bipolar electrode. Switching between these different modes can be accomplished through the use of a switching device 46 such as a multiplexing device or programmably switching device coupled to one or more conductive surface 14con, electrodes 18 and power supply 20.

page 54, paragraph starting on line 11

Referring to Figure [47]46, in a related embodiment conductive surface 14con can comprise one or more conductive areas 14cona which can each be individually controlled to an on/off state using coupled to switching device 46. The use of switching device 46 allows the user to dynamically increase or decrease the conductive area 14con of contact surface 14 to do one or more of the following: (i) adjust the area of conductive surface 14 con as an energy delivery electrode or return electrode to compensate for changes in tissue impedance; (ii) adjust the area of tissue heated; (iii) adjust the rate of tissue heating; and (iv) adjust the area of area of conductive surface as a return electrode in order to prevent thermal damage to non-target tissue including coagulation of blood vessels such as the hepatic vein.

page 55 paragraph starting on line 3

Referring to Figure [48]47, in related embodiments employing a conductive contact surface 14con as an electrode, one or more electrodes 18 can be selected as the positive

electrode 18p, using switching device 46 and so create a selectable composite vector(s) 18v of current or energy into target tissue 5' having a selectable direction and magnitude. The selection and configuration of electrodes 18 to produce a given vector can be controlled by logic resources 350 coupled to switching device 46 which can be a multiplexing device. The vector 18v can be in the volume 5ve defined by deployed electrodes 18, or the volume 5vec deployed electrodes 18 and conductive surface 14con. In use, this approach allows the physician to more precisely control or titrate the delivery of RF or others electromagnetic energy to yield higher current densities and hence temperatures in selected portions of the target tissue volume and lower current densities in other selected areas. This configuration in turn provides benefit of providing a higher degree of cell necrosis/[ablation]ablation with a lower risk of tissue desiccation and excessive impedance build up.

page 55 paragraph starting on line 19

Referring to Figure [49]48, in another embodiment one or more electrodes 18 and/or conductive surface 14 con can be configured to produce a phased array of RF electrode 18pa to obtain a zone or area of constructive signal interference 5ci within target tissue volume 5' under tissue surface 5s and hence an enhanced thermal effect with more rapid tissue heating and necrosis. Phased array embodiments can include use of conductive surface 14con as either a positive or electrode 18p, 18r. Electrodes 18 and/or conductive surface 14con can be coupled to a controller 339 described herein having logic resources (e.g. a microprocessor) 350 that adjusts the feedback signal, with a gradient search or matrix inversion algorithm known in the art, to provide a uniform electric field radiation into the target tissue site 5ci.

page 56, paragraph starting on line 5

Depending upon the location of the tumor it may be advantageous to operate in a bipolar mode so as not to have the return electrical current flow through a narrowed or small portion of the liver where the tissue impedance can be great enough to cause a temperature increase sufficient to coagulate or damage the hepatic vein or other hepatic vasculature. Accordingly, referring to Figures [51a and 51b]50a and 50b, in an embodiment impedance measurement circuitry and/or controller/logic resources 339/350 (coupled to power source 20) can be configured to determine if the return path impedance is sufficient to cause heating anywhere along the return path and automatically switch into a bipolar mode either prior to energy delivery or once such impedance or resulting temperature exceeds a

preselected threshold. In a related embodiment, thermal, flow and coagulation sensors 22 can be positioned in the hepatic vasculature within target site 5' or nearby tissue. Sensors 22 can monitor both the temperature of the hepatic vasculature as well as monitor blood flow rates there through the hepatic vasculature. Again sensors 22 are coupled to logic resources which switch from a monopolar to a bipolar mode, shut off or otherwise attenuate the delivery of power to target site 5' when: (i) the tissue temperature exceeds an absolute threshold or a rate of increase; (ii) the blood flow rate falls below an absolute threshold or a rate of decrease; or (iii) a combination of items (i) and (ii). In these and related embodiments, sensors 22 can be positioned on electrode 18 or passive non energy delivering members which can be positioned at varying distances from energy delivery devices 18 so as to be to passively monitor tissue temperatures at selected distances from electrode 18. Sensors 22 can be electronically coupled to logic resource in turn coupled to power source 20. Such resources can include microprocessors containing embedded modules or software programs. Such microprocessors can include an Intel® Pentium® III chip or a PowerPC® chip manufactured by the Motorola Corporation. Such resource can also contained embedded control modules that include process control algorithms known in the art such as PID algorithms. The switching between monopolar to bipolar modes can be achieved by the use of switching circuitry 20s including multiplexer devices (including a densely packed wavelength multiplexor) coupled to one or more electrodes 18 as wells as return electrode 18r and tissue contact surface 14 including conductive portions 14con. Switching to bipolar mode also serves to keep RF induced heating closer to tissue surface 5s thus preventing the unwanted heating of deeper tissue containing healthy tissue and/or thermally sensitive structures. Thus in use, embodiments having the ability to have feedback control to switch between monopolar and bipolar modes present the advantage of more refined and faster control over the depth of tissue heating to prevent thermal injury of underlying healthy/sensitive tissue without having to reposition the electrodes.

page 57, paragraph starting on line 22

Referring to Figures [51a, 51b and 52]50a, 50b, and 51, in another embodiment of the invention surface treatment apparatus 10 can comprise a collapsible strut apparatus 110 configured to be coupled to power source 20. Collapsible apparatus 110 can be configured to positionable within an endoscopic or a surgical introducing device 111 such as an endoscope, trocar and the like. Collapsible apparatus 110 has a collapsed or non deployed



position shown in [51a]50a and a deployed position shown in Figure [51b]50b. Collapsible apparatus 110 includes a central elongated or shaft member 112 having a distal section 112ds including an end 112de. A needle electrode 118n can be fixedly or movably attached to tip 112de. Also shaft member 112 can include a lumen 112l which can be configured to allow the advancement of a rigid or a flexible advancement member 116. Advancement member 116 can be flexible or rigid and can be guide wire, hypotube, or polymer shaft all having sufficient column strength to advance a distally coupled needle into tissue. Advancement member 116 can be coupled to a needle electrode 118n to allow its advancement into tissue.

page 58, paragraph starting on line 12

A movable proximal hub 120 is slidably positioned over shaft 112 and is configured to slides over distal section 112ds and can be releasably locked in position in position using a first locking device 120l which can be a latch, locking nut or clamp known in the art. A distal hub 126 is positioned over distal end 112de and preferably is fixedly mounted. However the longitudinal position of hub 126 with respect to shaft longitudinal axis 112al can be adjusted using a second locking device 126l. Alternatively, in embodiment shown in Figure [52]51, distal hub 126 can be movable and proximal hub 120 can be fixed. Also, proximal hub 120 can comprise an overtube 120ot that is slidably positioned over shaft 112. Both of hubs 120 and 126 can be configured to be advanced and retracted by a coupled guidewire or other mechanical linkage known in the art. In an embodiment one, or both of hubs 120 and 126 can include a flange 121f or 126f that enables one or both hubs to be pushed (advanced) and pulled back via means of either stiffened guide wires mechanically coupled (e.g. by welding) to either flange or a hollow advancement tube member 130 that is coupled to or otherwise pushes up against either flange. In yet another embodiment either flange 121f or 126 f can be configured to act as pneumatic or fluidic seal against the lumen of an overlying introducer 111 such that either hub can be and retracted so as to deploy and retract electrodes 118 pneumatically or hydraulically using an air or fluid pressure source 140 known in the medical device arts. An example of air pressure source includes a tank of compressed gas and a fluid pressure source includes a syringe pump.

page 63, paragraph starting on line 17

Referring now to Figures [54a and 54b]53a and 53b, in an alternative embodiment expansion device 129 can comprise an expandable balloon device known in the art such as a

dilatation balloon known in the art. Guide tubes 128 can be distributed along a perimeter 129p or a portion thereof of balloon device 128. Balloon device 129 can be coupled to guide tubes 128 using adhesive bonding and other polymer bonding methods known in the art (or alternatively balloon device 129 and guide tubes 128 can be integrally formed). Balloon 129 is expanded to a selectable diameter to achieve a selected spacing or diameter 134d of a geometric shape whose perimeter is defined by deployed guide tubes 128. The shape or diameter of this shape in turn defines the collective shape or pattern 134 of deployed electrodes 118. The degree of inflation of balloon 129 can be used to match the diameter of deployed shape 134 to that of the tumor mass 5" or selected target tissue site 5'.

page 65, paragraph starting on line 3

In an alternative embodiment shown in Figure [54b]53b a sizing or restraining member 131 can be disposed over balloon 129 and used to control the maximum inflated diameter 129d of balloon 129 as well as the inflated shape of balloon 129. The sizing member can be coupled to the proximal and distal portions of balloon 129 and can comprise a DACRON sheath or other collapsible yet substantially non-compliant material known in the biomedical material arts including polyesters, PET and the like.

page 69, paragraph starting on line 3

Referring now to Figure [55]54, all or portions of feedback control system 329 are illustrated. Current delivered through RF electrodes 314 and 316 (also called primary and secondary RF electrodes/antennas 314 and 316) is measured by a current sensor 330. Voltage is measured by voltage sensor 332. Impedance and power are then calculated at power and impedance calculation device 334. These values can then be displayed at a user interface and display 336. Signals representative of power and impedance values are received by controller 338 which can be a microprocessor 338.

page 71, paragraph starting on line 21

Referring now to Figure [56]55, current sensor 330 and voltage sensor 332 are connected to the input of an analog amplifier 344. Analog amplifier 344 can be a conventional differential amplifier circuit for use with sensors 324. The output of analog amplifier 344 is sequentially connected by an analog multiplexer 346 to the input of A/D converter 348. The output of analog amplifier 344 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D

converter 348 to a microprocessor 350. Microprocessor 350 may be Model No. 68HCII available from Motorola. However, it will be appreciated that any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

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